

10/509252

DT04 Rec'd PCT/PTO 28 SEP 2004

PATENT  
12480-000069/US

#4

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant(s): Shunichi KURODA et al.  
Int'l App. No.: PCT/JP03/02600  
Application No.: **NEW APPLICATION**  
Filed: September 28, 2004  
For: DRUGS FOR TREATING HEPATIC DISEASES WITH THE USE  
OF HOLLOW PROTEIN NANOPARTICLES

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**INFORMATION DISCLOSURE STATEMENT  
(SUBMISSION CONCURRENT WITH THE  
FILING OF A NEW PATENT APPLICATION)**

U.S. Patent and Trademark Office  
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September 28, 2004

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- ☐ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- ☒ This application is a National Phase of a PCT application. All of the documents listed on the PTO-1449 are not enclosed because they were cited in the International Search Report and copies should be forwarded from the International Search Authority. If copies are needed, please contact the undersigned.

- ☐ Because the present application is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

a. ☒ **DOCUMENTS IN THE ENGLISH LANGUAGE**

The attached patents, publications, or other information in the English language do not require a statement of relevancy.

b. ☒ **DOCUMENTS NOT IN THE ENGLISH LANGUAGE**

A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

Many of the documents have been discussed in the PCT Search Report, the PCT Preliminary Examination Report, and/or throughout the specification. The PCT Search Report and/or PCT Preliminary Examination Report, indicate the degree of relevance found by the PCT Office, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

c. ☒ **ENGLISH LANGUAGE SEARCH REPORT**

An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(A)(3).

d. ☒ **OTHER**

The following additional information is provided for the Examiner's consideration.

For Examiner's consideration a copy of International Search Report and International Preliminary Examination Report are submitted herewith.

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New PCT National Phase Application  
Docket No. 12480-000069/US

FEES

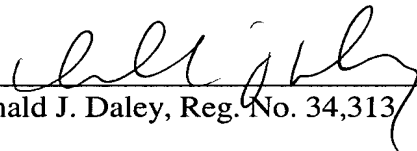
This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

If The Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 08-0750.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C

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Enclosures: ☒ Form PTO-1449(s)  
☒ Documents  
☒ Foreign Search Reports

<b>Form PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  (Use several sheets if necessary)	<b>ATTY DOCKET NO.</b> 12480-000069/US	<b>APPLICATION NO.</b> NEW APPLICATION
	<b>APPLICANTS</b> Shunichi KURODA et al.	<b>CONF. NO.</b> Unknown
	<b>FILING DATE</b> September 28, 2004	<b>GROUP</b> Unknown

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
						YES	NO
	CA 2,131,415	09/05/1995	CANADA			Yes	
	WO 01/60415 A1	08/23/2001	WIPO			Yes	
	WO 9609074 A1	03/28/1996	WIPO			Yes	
	WO 96/21014	07/11/1996	WIPO			Yes	
	WO 01/93836 A2	12/13/2001	WIPO			Yes	
	WO 01/64930 A1	09/07/2001	WIPO			Abst	
	EP 0 201 416	11/12/1986	EUROPE				No

**OTHER DOCUMENTS**

(Include Name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.

	Shun'ichi KURODA et al., "Hepatitis B Virus Envelope L Protein Particles", Synthesis and Assembly in Saccharomyces Cerevisiae, Purification and Characterization, The Journal of Biological Chemistry, Vol. 267, No. 3, 1992, Pgs. 1953-1961
	Cheng QIAN et al., "Induction of Sensitivity to Ganciclovir in Human hepatocellular Carcinoma Cells by Adenovirus-Mediated Gene Transfer of Herpes Simplex Virus Thymidine Kinase", The American Association for the Study of Liver Diseases, Pgs. 118-123
	H OKADA et al., "Effective cytokine gene therapy against an intracranial glioma using a retrovirally transduced IL-4 pus HSVtk tumor vaccine", Gene Therapy (1999) 6. 219-226
	F. DELPEYROUX et al., "Insertions in the Hepatitis B Surface Antigen Effect on Assembly and Secretion of 22-nm Particles from Mammalian Cells", J. Mol. Biol (1987) 195, 343-350
	Tadanori YAMADA et al., "B-gata Haien Virus Hyomen Kogen Nano Ryushi O Mochiita Atarashii Idenshi Donyu-ho no Kaihatsu", Kagaku Kogakkai Nenkai Kenkyu Happyo Koen Yoshishu, March 2, 2001, 66 <sup>th</sup> , Pgs. 271, F307
	Shunichi KURODA et al., "A New Pinpoint Gene Delivery System Using Genetically Engineered Hepatitis B Virus Envelope L Particles", Materials Integration Vol. 15 No. 7, 2002 Pgs. 12-17
	Masaru MURAOKA et al., "Drug Delivery o Mezashita Tokui-sei Kaihen-gata B-gata Haien Hyomen Kogen Chuku Nano Ryushi no Kaihatsu", Kagaku Kogakkai Nenkai Kenkyu Happyo Koen Yoshishu, February 23, 2003, 68 <sup>th</sup> , Pgs 443 L304

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.